K030763

MAR 2 6 2003

## SECTION 4.2.14
## 510(K) SUMMARY

| **PREDICATE DEVICE**<br>**Diagnostic Ultrasound BladderScan™**<br>**BVI 6100 Ultrasound System** | **New DEVICE**<br>**Diagnostic Ultrasound BladderMass™**<br>**BVM 6500 Ultrasound System** |
|---|---|
| Predicate: The BladderScan™ BVI 6100 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume noninvasively. The BladderScan BVI 6100 is contraindicated for fetal use and for use on pregnant patients. | New device: The BladderMass™ BVM 6500 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume and bladder wall mass noninvasively. The BladderMass BVM 6500 is contraindicated for fetal use and for use on pregnant patients. |

510(k) Summary
(As required by 21 CFR 807.92(a))

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| A. | Submitter Information | Compay: Diagnostic Ultrasound<br>21222 30th Drive SE, Suite 120<br>Bothell, WA 98041<br>Phone: 425-867-1348 ext.1667<br>Fax: 425-883-2896<br>Email: ngertlar@dxu.com<br>Contact: Nancy J. Gertlar, RAC<br>Director, Regulatory Affairs<br>Date: March 5, 2003 |
| B. | Device Information | |
| | Trade/Proprietary Name: | Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System |
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| | Common Name: | Diagnostic Ultrasound System with Accessories |
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| | Classification Name: | Regulatory Class: II<br>Review Category: Tier II<br>Classification Panel: Radiology<br>Ultrasonic Pulsed Echo Imaging System<br>• FR Classification 892.1560<br>• Product Code 90-IYO<br>Diagnostic Ultrasound Transducer<br>• FR Classification 892.1570<br>• Product Code 90-ITX |
| | | |
| | Predicate Device: | Diagnostic Ultrasound BladderScan BVI 6100 Ultrasound System, K022153 |
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| | Device Description: | The Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System is a hand-held, battery powered, software controlled ultrasound system used to acquire and display real time B-mode images of the bladder. The system is intended to non invasively monitor bladder volume on an intermittent basis. The ~~system is an effective, low cost, simple option for use in a clinical hospital or~~ |

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| | | system is an effective, low cost, simple option for use in a clinical hospital or nursing home setting or for home use under medical supervision. |
| | Intended Use: | New device: The BladderMass™ BVM 6500 is intended to project ultrasound energy through the lower abdomen of the nonpregnant patient to obtain an image of the bladder and uses that image to calculate the bladder volume and bladder wall mass noninvasively. The BladderMass 6500 is contraindicated for fetal use and for use on pregnant patients. |
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| C. | Comparison of Required Technological Characteristics: | The Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System and its integrated 3.7 MHz mechanical sector transducer operate only in B-mode to locate and automatically measure bladder volume. Bladder volume, patient gender, non optimal directional aiming, battery status, and usage rate indicators are all displayed on the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System scanner. The ultrasonic power transmitted the system is not user adjustable.<br><br>The hand-held Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System is applied to the patient's abdomen with a single patient use Sontac® hydrogel pad, manufactured by Diagnostic Ultrasound to optimize the performance of the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System. The transducer collects cross- sectional images of the bladder from twenty four (24) scan planes. From this information, the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System constructs a finite element model of the bladder and automatically computes the volume of urine via volumetric integration and the bladder wall mass.<br><br>In order to demonstrate the BladderMass accuracy claimed in 0270-1238-xx-55, a third party vendor was contracted to build tissue |

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| | | equivalent phantoms with known dimensions. The suppliers, Computerized Imaging Reference Systems (CIRS) is known for supplying medical imaging phantoms to the medical marketplace.<br><br>The BladderMass Phantom is essentially a balloon which gets filled with urine mimicking material and then the filled balloon is surrounded with tissue mimicking material. Both the tissue and urine mimicking material have been used by CIRS for many years in bladder volume phantoms. The balloon is injected molded to have a thickness of approximately 3mm when relaxed, due to the precision of the injection molded process this thickness does not vary by more than +/- 0.25 mm across the surface of the balloon.<br><br>Different urine volumes and thus different bladder wall thickness measurements can be made by filling the balloon with different amounts of urine mimicking material. Since the same mold is used for both balloons, the balloon mass will be relatively constant between phantoms while the bladder wall thickness and urine volume can change significantly.<br><br>During the manufacturing process, CIRS measures key parameters of the physical parts as the parts are constructed. These measurements are all NIST traceable and each phantom comes with a certification sheet listing the measurements.<br><br>These results obtained through the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System are compared to the expected results derived from the NIST traceable measurements. In addition to these measurements, additional measurements are taken by standard ultrasound systems, such as the Sonosite 180, to compare bladder mass measurements.<br><br>The traditional method of measuring bladder mass is to use a standard ultrasound system, |

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| | | make random bladder wall measurements, and calculate the expected bladder wall mass.<br><br>The Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System takes measurements of the bladder wall and calculates the bladder wall mass.<br><br>Accuracy has been demonstrated by comparing CIRS measurements to the measurements of the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System.<br><br>A Calibration Targeting System, consisting of a heli-coil shaped calibration target along with a specially designed container, allows the user to easily scan a known geometrically shaped target. Data may be optically transmitted to a remote location when connected to the clinician's personal computer via a communication cradle. Connection to this communication cradle allows for battery charging, remote calibration, usage monitoring, software updates, and data transfer through a web-based interface, referenced as "ScanPoint™". The Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System also includes a universal charger cradle for the non replaceable lithium ion battery incorporated into the hand held instrument. |
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| D. | Summary and Conclusion of Non Clinical and Clinical Testing | All clinical and non clinical testing of the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System indicate that the Diagnostic Ultrasound BladderMass BVM™ 6500 Ultrasound System is substantially equivalent to the Diagnostic Ultrasound BladderScan™ BVI 6100 Ultrasound System, and all acoustic measurements remain within Preamendment limits. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2003

Diagnostic Ultrasound Corporation
% Mr. Heinz Joerg Steneberg
Responsible Third Party
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K030763
Trade/Device Name: Diagnostic Ultrasound BladderMass BVM 6500
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic trensducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: March 7, 2003
Received: March 11, 2003

Dear Mr.Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

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| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

**System: BladderMass™ BVM 6500 Ultrasound System**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | |
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| **General (Track I only)** | Specific (Tracks I & III) | B | M | PWD | CWD | Color Doppler | Combined (Spec.) | Other (Spec.) |
| Ophthalmic | Ophthalmic | | | | | | | |
| **Fetal Imaging & Other** | Fetal | | | | | | | |
| | Abdominal | P | | | | | | |
| | Intra-operative (Abdominal organs and vascular) | | | | | | | |
| | Intra-operative (Neuro.) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (breast, thyroid, testicles) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | |
| | Musculo-skel. (Convent.) | | | | | | | |
| | Musculo-skel. (Superfic.) | | | | | | | |
| | Intra-luminal | | | | | | | |
| | Other (spec.) | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Trans-esophageal (card.) | | | | | | | |
| | Other (spec.) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | | | | | | | |
| | Other (spec.) | | | | | | | |

N= new indication; P= previously cleared by FDA (K022153)

Prescription Use (Per 21 CFR 801.109) David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030763